

K251382 Phoenix Sinus Tarsi Stent SystemAug 27, 2025
117 days to decisionK251382 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k251382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	May 2, 2025
Decision date	Aug 27, 2025
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Astra Orthomed, Inc.
Location	Brentwood, TN, US
Contact	Michael Graham
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Secure BioMed Evaluations
Contact	Justin Gracyalny

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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